

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Gel-One (sodium hyaluronate)
BILLING CODE	J7326
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Durolane, Supartz FX, Gelsyn-3 QUANTITY LIMIT— 1 injection (1 unit)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Gel-One (sodium hyaluronate) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOARTHRITIS OF THE KNEE

For **initial** authorization:

1. Member must be 40 years old or older; AND
2. Member must have a diagnosis of osteoarthritis confirmed by radiological evidence (e.g. Kellgren-Lawrence Scale score of grade 2 or greater); AND
3. Medication must be prescribed by an orthopedic surgeon, interventional pain physicians, rheumatologists, physiatrists (PM&R) and all sports medicine subspecialties; AND
4. Member tried and failed an intra-articular corticosteroid injection(s) in which efficacy was < 4 weeks duration; AND
5. Documentation that member tried and failed ALL of the following:
 - a) Weight loss attempts or attempts at lifestyle modifications to promote weight loss (only for members with BMI \geq 30); AND
 - b) Sufficient trial (e.g. 2 to 3 months) of non-pharmacologic therapies (bracing/orthotics, physical/occupational therapy); AND
 - c) At least 3 simple analgesic therapies (acetaminophen, NSAIDs, oral or topical salicylates); AND
6. Member is not using medication for hip or shoulder related conditions;
7. Member has tried and failed to respond to treatment with Supartz FX or Durolane or Gelsyn-3 (documented in chart notes and confirmed by claims history).
8. **Dosage allowed:** Inject 30 mg (3 mL) once.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must have documented significant pain relief that was achieved with the initial course of treatment; AND
2. Initial course of treatment has been completed for 6 months or longer; AND
3. Member meets all of the criteria for the initial approval.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.



CareSource considers Gel-One (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Refractory interstitial cystitis
- Arthropathy - Disorder of shoulder
- Intravitreal tamponade
- Keratoconjunctivitis sicca
- Subacromial impingement, Syndrome of the shoulder

DATE	ACTION/DESCRIPTION
05/17/2017	New policy for Gel-One created. Minimum age and BMI requirements changed. Limits of additional courses of treatment changed.
05/15/2018	Changed to non-preferred status. Trial of Supartz FX or Gel-One or Durolane added to criteria.

References:

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12. Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and meta-analysis. *Ann Rheum Dis*. 2007; 66(4):433-9.
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16. Leighton R, Åkermark C, Therrien R, et. al. NASHA hyaluronic acid vs methylprednisolone for knee osteoarthritis: a prospective, multi-centre, randomized, non-inferiority trial. *Osteoarthritis Cartilage*. 2014; 22(1):17-25.



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